Nicolet
BIOMEDICAL

K020955

APR 17 2002

Summary of Safety and Effectiveness

Company Name:	Nicolet Biomedical 5225 Verona Road Madison, WI 53711
Contact: Phone: Fax:	Glen Hermanson, Manager of Standards and Compliance 608 441-2065 608 441-2007
Summary Date:	March 20, 2002
Trade Name:	Electrocautery Detector
Common Name:	Nerve Stimulator
Classification Name:	21 CFR 874.1820; Product Code: ETN

Predicate Device:

510(k) Number:	K934426
Manufacture:	XOMED-TREACE, Inc.
Trade Name:	Nerve Integrity Monitor-2 (NIM-2 XL)

1.0 Description of Device

The Nicolet Electrocautery Detector interfaces between the auditory signal output from a nerve monitor and the nerve monitor's external speaker. The Electrocautery Detector automatically mutes the nerve monitor speaker when electrocautery interference is detected.

2.0 Intended Use

The intended use of the Nicolet Electrocautery Detector is as an accessory device supporting muting of external audible outputs when electrocautery interference is detected.

3.0 Technological

The technology of the Electrocautery Detector is equivalent to the electrocautery mute feature in the predicate device. Both devices detect the presence of electrocautery RF energy as an interference signal and mute the speaker.

4.0 Conclusions

The intended use and technology of the Nicolet Electrocautery Detector device is substantially equivalent to the predicate device, electrocautery mute feature. No new questions of safety or effectiveness are raised.

5.0 Specifications/Comparison to Predicates

Table 5.0-1 compares features and specifications of the Nicolet Electrocautery Detector to the predicate device.

Table 5.0-1: Nicolet Electrocautery Detector Comparison to Predicate XOMED NIM-2 XL

Feature	Nicolet Electrocautery Detector Device (Under Review)	XOMED NIM-2 XL (Predicate K934426)	Substantial Equivalence Comments
Indication for Use	The Nicolet Electrocautery Detector is an accessory device supporting muting of external audible outputs when electrocautery interference is detected.	As a feature of nerve monitoring, an electrocautery detection and muting feature is provided.	Same features with regard to electrocautery detection and muting of audible output.
Environment of Use	Wherever nerve monitors and stimulators are used. Typically hospitals and clinics.	Hospitals and clinics	Used in the same clinical environments.
Number of electrocautery detector inputs	2	4	Up to 2 electrocautery antenna probe inputs are supported on the Electrocautery Detector.
Technology	Detection of electrocautery Radio Frequency energy and muting of audible output.	Detection of electrocautery Radio Frequency energy and muting of audible output.	Same
Recovery Time After Mute	$\leq$ 1 second	$\leq$ 5 seconds	The Nicolet Electrocautery Detector has a faster recovery time from a muted condition.
Electrocautery Detector Sensitivity Adjustment	Yes - User selectable	Yes - User Selectable	Same
Adjustable Sensitivity to Electrocautery Interference Detection	Yes	Yes	Same

Table 5.0-1: SNAP Device Comparison to Predicates, continued			
Feature	**Nicolet Electrocautery Detector Device (Under Review)**	**XOMED NIM-2 XL (Predicate K934426)**	**Substantial Equivalence Comments**
Power Source	DC - Battery or Rechargeable Battery	DC - Rechargeable Battery	Equivalent
Battery Life	$\geq$ 3 months	4 to 6 Hours	The batteries in the Electrocautery Detector are only powering the muting functions, not a mute function and nerve monitoring as in the predicate NIM-2 XL.
Low Battery Indication	Audible and visual	Audible and visual	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 17 2002

Nicolet Biomedical, Inc
c/o Gary Syring, Principal Consultant
Quality and Regulatory Associates, LLC
800 Levanger Lane
Stoughton, WI 53589

Re: K020955
Trade/Device Name: Nicolet Electrocautery Detector
Regulation Number: 21 CFR 874.1820
Regulation Name: Surgical Nerve Stimulator/Locator
Regulatory Class: Class II
Product Code: ETN
Dated: March 20, 2002
Received: March 25, 2002

Dear Mr. Syring:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K020955

Device Name: Nicolet Electrocautery Detector

Indications For Use:

The Nicolet Electrocautery Detector is an accessory device supporting muting of external audible outputs when electrocautery interference is detected.

(PLEASE: DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

Prescription Use yes ✓
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K020955